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Joseph Weathered

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANT(S)	:	Naomi L. NAKAO
SERIAL NO.	:	10/670,106
FILED	:	09/24/2003
FOR	:	Medical Instrument for Fluid Injection and Related Method
GROUP ART UNIT	:	3767
EXAMINER	:	Elizabeth MacNeil

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF BRIEF ON APPEAL

S I R:

Enclosed herewith an Appeal Brief in the above-identified application.

Also enclosed is a check in the amount of Eight-Hundred-and-Twenty-Five Dollars ($825.00), which amount includes Two-Hundred-and-Seventy Dollars ($270.00) in payment of the fee for filing a Brief on Appeal by a small entity. Small entity status applies to this application.

Please charge any additional fees due in connection with this communication to Deposit Account No. 04-0838. A copy of this Transmittal is enclosed for deposit account charging purposes.

Respectfully submitted,
COLEMAN SUDOL SAPONE, P.C.

Dated: 29 December 2008

By: _____
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BRIEF ON APPEAL

1. REAL PARTY IN INTEREST

The real party of interest in the present application is Granit Medical Innovations, LLC, a limited liability company formed under the laws of the

State of New York, having a primary business address at 992 Fifth Avenue, New York, New York 10028. Granit Medical Innovations, LLC owns the entire right, interest, and title to the present application by virtue of an Assignment recorded in the assignment records of the Patent and Trademark Office at Reel No. 016996, Frame No. 0113 et seq. Granit Medical Innovations, LLC, acquired the entire right, interest, and title to the present application from predecessor corporation, Granit Medical Innovations, Inc., a corporation formed under the laws of the State of New York, having a primary business address at 992 Fifth Avenue, New York, New York 10028. Granit Medical Innovations, Inc., previously acquired the entire right, interest, and title to the present application from the inventor by virtue of an Assignment recorded in the assignment records of the Patent and Trademark Office at Reel No. 014222, Frame No. 0320 et seq.

2. STATEMENT OF RELATED CASES

There are currently no prior or pending appeals, interferences or judicial proceedings – known to any inventors, any attorneys or agents who prepared or prosecuted the above-identified appeal or any other person substantively involved in the preparation or prosecution of the application on appeal – that are related to, directly affect, or would be directly affected by, or have a bearing on the Board's decision in the present appeal.

3. JURISDICTIONAL STATEMENT

The present appeal is taken under 35 U.S.C. § 134.

The present appeal is taken from the rejection in an Office Action mailed 25

March 2008.

The Notice of Appeal was filed 29 July 2008.

The present Appeal Brief is being filed by mail certificate dated 29 December 2008.

4. TABLE OF CONTENTS

The present Appeal Brief includes the following items, beginning on the pages listed:

5. TABLE OF AUTHORITIES

6. STATUS OF AMENDMENTS

All Amendments have been entered. No Amendments were submitted after the Final Office Action of 25 March 2008.

7. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal is the rejection of claims 1 and 3-5 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,536,267 to Edwards et al. ("Edwards") in view of U.S. Patent No. 5,354,279 to Höfling.

8. STATEMENT OF FACTS

As set forth in claim 1, an endoscopic medical instrument comprises an elongate tubular member 22 with a lumen and a plurality of hollow needle elements 20 connected to one end of the elongate member so that each of the hollow needle elements communicates with the lumen of the elongate tubular member. (Specification page 20, lines 8-12.) The elongate tubular member 22 is sufficiently flexible, long and narrow to traverse a biopsy channel of a flexible fiberoptic endoscope. (Specification page 6, lines 13; page 20, lines 22-22; page 22, lines 3-4.) The needle elements 20 extend in a direction away from the one end of the elongate tubular member and are each convex on an outer side facing away from the other needle element and concave on an inner side facing the other needle elements so that the needle elements together define a bulbous ovoid shape, with tips of the needle elements angled inwardly at a distal tip of the medical instrument. (Page 21, lines 9-13.) The needle elements each are sufficiently flexible to negotiate bends in the biopsy channel. (Page 4, lines 12-15; page 8, lines 11-13; page 17, lines 21-22; page 18, lines 8-9; page 21, lines 4-8; page

Figure 3.) Each of the hollow needle elements is provided with at least one aperture so that fluid may be delivered through the elongate tubular member and the hollow needle elements and out through the apertures in the hollow needle elements. (Page 7, lines 14-15; page 21, lines 16-18.)

The Edwards reference discloses a generally rigid (see Fig. 1) multiple electrode ablation apparatus (title) having a plurality of hollow electrodes 20 (col. 6, lines 22-28) each extending longitudinally through a guide catheter 12 (Figures 6 and 7; col. 6, lines 20-25). The electrodes 20 pass longitudinally through the catheter 12 and out through a closed distal end of the catheter (col. 6, lines 22-25; Figures 6 and 7). The electrodes 20 are slidable longitudinally relative to the catheter 12 so that the distal ends of the electrodes can move alternately into and out of the catheter (col. 6, lines 24 and 25, 33; compare Figures 6 and 7). Generally, the electrodes 20(b) are in retained positions while they are non-deployed, this being achieved by a variety of methods: (i) the electrodes are pre-sprung, confined in delivery catheter 12, and only become sprung (expanded) as they are released from delivery catheter 12, (ii) the electrodes are made of a memory metal, (iii) the electrodes are made of a selectable electrode material which gives them an expanded shape outside of delivery catheter 12, or (iv) delivery catheter 12 includes guide tubes which serve to confine electrodes 12 within delivery catheter 12 and guide their direction of travel outside of the catheter to form the desired, expanded ablation volume. (Col. 7, lines 7-23.)

The Edwards reference does not disclose any structure at the proximal ends of the electrodes. The Edwards disclosure with respect to the electrical circuitry is schematic (see Fig, 21 and attendant discussion at col. 10, lines 40-61.) and does not specify electrical connections or contacts. Edwards does disclose that a cam 22 or other actuating device, can be positioned within delivery catheter and used to advance and retract electrodes 20 in and out of delivery catheter 12. (Col. 7, lines

59-61.)

Edwards discloses further that the electrodes 20 can be segmented and include a plurality of fluid distribution ports 26 that permit the introduction and flow of a variety of fluidic mediums through electrode 20 to a desired tissue site, such fluidic mediums including electrolytic solutions, pastes or gels, as well as chemotherapeutic agents. (Col. 8, last line, through col. 9, line 8.)

The Höfling reference discloses a catheter for the injection of a fluid through multiple bent hollow needles 26 (col. 4, lines 29-31) into a wall of a vein or other hollow internal organ (col. 1, lines 5-7, 49-51). In a first embodiment, each needle element 26 is mounted in a distal end of a respective passage or lumen 24 of a hose 20 that is longitudinally slidable within an outer catheter shank 12. The outer shank 12 is firmly connected to a stationary part 34 of an operating mechanism 32, while the inner hose 20 is connected to a movable part 35 of the operating mechanism. (Col. 5, lines 27-30.) The hollow needles 26 communicate with a side socket 45 and a distribution chamber 46 via respective passages or lumens 24 (col. 5, lines 47-48) in the tubular hose member 20 (Figure 3). The same structure of needle elements having their own dedicated feed channels is present in all of the embodiments of the Höfling injection catheter assembly.

The Examiner relies on Figures 1 and 2: "Höfling teaches an elongate member (12) with a lumen (Fig. 1) and multiple needle elements (26) which communicate with the lumen of the elongate member (Fig. 1, 2). The needle elements all communicate with a lumen (46) of the elongated member." (Last sentence of Detailed Action page 2, Office Action of 25 March 2008.)

9. ARGUMENT

A. Rejection of Independent Claim 1 Under 35 U.S.C. §103(a)

Claim 1 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over

U.S. Patent No. 5,536,267 to Edwards et al. ("Edwards") in view of U.S. Patent No. 5,354,279 to Höfling.

Appellant traverses the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a) and maintains that claim 1 distinguishes the invention over the prior art and particularly over Edwards in view of Höfling.

As set forth in claim 1, an endoscopic medical instrument comprises an elongate tubular member with a lumen and a plurality of hollow needle elements connected to one end of the elongate member so that each of the hollow needle elements communicates with the lumen of the elongate tubular member. The elongate tubular member is sufficiently flexible, long and narrow to traverse a biopsy channel of a flexible fiberoptic endoscope. The needle elements extend in a direction away from the one end of the elongate tubular member and are each convex on an outer side facing away from the other needle element and concave on an inner side facing the other needle elements so that the needle elements together define a bulbous ovoid shape, with tips of the needle elements angled inwardly at a distal tip of the medical instrument. The needle elements each are sufficiently flexible to negotiate bends in the biopsy channel. Each of the hollow needle elements is provided with at least one aperture so that fluid may be delivered through the elongate tubular member and the hollow needle elements and out through the apertures in the hollow needle elements.

Appellant's invention is particularly designed for use in a flexible endoscopic procedure to raise polyps from a colon wall so that the polyps may be removed without perforating the colon. An endoscopic medical instrument in accordance with Appellant's claimed invention is deployable via a working channel of a flexible endoscope and includes an end effector with a plurality of needles that are disposable around a poly head and insertable into the tissue at the base of the polyp for providing the polyp with a pedicle or neck suitable for

severing via a cauterization snare. Appellant's invention provides a completely new instrument in the diagnosis and treatment of colon cancer and renders polypectomies safer.

Appellant's invention is workable in part because of the communication of the multiple needle elements with the lumen of the elongate tubular member to which the needle elements are connected. This enables a flexible small-diameter instrument that can fit down a working channel of a flexible endoscope and deliver suitable streams of liquid via all the needle elements.

The Edwards reference relates to a multiple electrode ablation apparatus having a plurality of hollow electrodes 20 each extending longitudinally through a guide catheter 12 (Figures 6 and 7). In the device of Edwards, the electrodes (20) pass longitudinally along the catheter and out through a closed distal end of the catheter 12. The electrodes are longitudinally slidable through the catheter.

Edwards does not have any disclosure pertaining to the proximal ends of the electrodes 20. However, there must be an electrical connection between the electrodes and an electrical current source. Proximal ends of the electrodes are presumably located outside the catheter at the proximal end thereof in order to connect to the current source. Edwards does not specify how liquid is delivered to the electrodes. One of ordinary skill in the art would likely conclude that liquid flows through each of the electrodes separately and does not flow from the catheter into the electrodes.

Edwards does not teach or suggest that the electrodes might communicate at their proximal ends with the lumen of the catheter. The Examiner agrees with this appraisal of Edwards and has stated, "Edwards does not teach that the proximal end of the needle elements communicates with the end of the tubular member so that fluid may be delivered through the elongate tubular member into the hollow needle elements." (Office Action of 25 March 2008, Paragraph 2 of Detailed

Action, penultimate paragraph.) Instead, the Examiner erroneously relies on Figures 1 and 2 of the Höfling reference as teaching multiple needle elements all communicating with the same lumen of a catheter. It is submitted that the Examiner's reliance on the Höfling reference is misplaced inasmuch as the tubular hose member 20 of that reference does not terminate near the distal end of the catheter shank 12 as the Examiner evidently assumes from a casual review of Höfling Figures 1 and 2. Rather, the tubular hose member 20 extends all the way to the proximal end of the catheter shank and the needle elements 26 (via their associated passages or channels 24) do not communicate with the lumen of the catheter shank 12. Figures 1 and 2 schematically depict the tubular hose member 20 broken away, as represented by the irregular line at the lower end of the tubular hose member 20. The Examiner has misinterpreted Figures 1 and 2 owing to a hindsight attempt to read features of Appellant's invention into the prior art and particularly the Höfling reference.

The Höfling reference discloses a catheter for the injection of a fluid through multiple bent hollow needles (26) into a wall of a vein or other hollow internal organ. In a first embodiment, relied on by the Examiner, each needle element (26) communicates with a fluid source (45, 46 in Figure 3) via respective lumens (24) in a tubular hose member (20) that is slidably disposed inside an introducer catheter (38). The same structure of needle elements having their own dedicated feed channels is present in all of the embodiments of the Höfling injection catheter assembly. This is in contrast to applicant's invention as set forth in amended claim 1, where each of multiple hollow needle elements communicates with the same lumen of the elongate tubular member.

Even if the Höfling reference taught multiple hollow needles all communicating with the lumen of a single catheter or tubular member, it would not be obvious to modify the Edwards device to have multiple needles communicating

with a single lumen. The needles of the Edwards device are electrodes. There must be conduction of not only fluid through the electrodes but also electrical current. With the needles extending all the way back to proximal end of the instrument, the electrical connections are clear and well within the level of skill in the art. If the needles were all to communicate with a single lumen, as proposed by the Examiner, it is not at all clear how the electrical current would be carried. Without a proper electrical signal path, the Edwards device would not work for its intended purpose – tissue ablation. There is nothing in the Höfling reference that would help one of ordinary skill in the art in reconfiguring the electrical circuit paths of the Edwards device to accommodate the modification in fluid flow paths proposed by the Examiner.

The Examiner maintains that it would be obvious to modify the electrocautery ablation device of Edwards to have the hollow needles communicate with the lumen of the tubular support or introducer member. The Examiner cites the following excerpt from Höfling (col. 5, lines 17-20):

> If several needles are required because of the greater stability and the possibility to introduce a greater amount of medicine, the inner hose 20 is preferably a multi-lumen hose.

The Examiner contends that this excerpt implies that multiple needles can be connected to a single lumen.

Applicant respectfully traverses the Examiner's reading of the Höfling excerpt and maintains that the reading is skewed by the hindsight provided by applicant's claimed invention. Rather than reading the excerpt in the light of applicant's claims, the excerpt should be read in the light of Höfling's own

disclosure, particularly the immediately preceding passage (col. 5, lines 8-16):

> In order to provide good support at least three needles should be utilized. However any number of needles may be used and they can be evenly or unevenly distributed over the cross-section of the head. With a larger number of needles also the amount of medicine admitted through the needles can be increased. With very narrow vessels or veins however there may not be sufficient space for a large catheter. Then also only a single needle may be used.

In the excerpt relied on by the Examiner, Höfling is contrasting a single needle with multiple needles, not multiple needles with more needles. Multiple needles provide greater stability than one needle. Three needles provide "good support." Two needles would provide more support than one needle and four needles would provide more support than three needles. In addition, the greater the number of needles the more medicine that could be delivered to the target tissues. Multiple needles are connected to multiple lumens, a single needle is connected to a single lumen.

The above argumentation, as well as the Statement of Facts hereinabove, includes a discussion of the scope and content of the cited prior art, pursuant to the requirements of case law. See, e.g., Dystar Textilfarben GmbH v. C.H. Patrick Co., 464 F.3d 1356, 1360 (Fed. Cir. 2006)(citing Graham v. John Deere Co., 383 U.S. 1, 17-18, S. Ct. 684, 15 L. Ed. 2d 545 (1966)). The above argumentation also contains a discussion of the differences between the claimed invention and the prior art, pursuant to same case law, id. Pursuant to observations made above with respect to the Edwards reference, Appellant submits that one of ordinary skill in the art (see, the same case law, id.) would not be inclined to provide or capable of providing the flow structure of Appellant's claimed medical instrument in the device of Edwards. One of ordinary skill in the art could not change the flow

structure (multiple needles with dedicated flow lines) of both the Edwards and the Höfling reference to a different structure. This conclusion is not inconsistent with the most recent pronouncements of the U.S. Supreme Court. See KSR International Co., v. Teleflex Inc., 127 S.Ct. 1727, 167 L. Ed. 2d, 705 (2007).

10. CONCLUSION

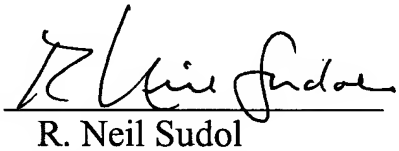
In summary, the Edwards and Höfling references do not render claims 1 and 3-5 obvious.

For the foregoing reasons, the rejection of independent claim 1 as well as dependent claims 3-5 under 35 U.S.C. §§ 103(a) is deemed to be improper. Appellant therefore urges that the Examiner be reversed and the application remanded for proceedings towards issuance.

Respectfully submitted,

COLEMAN SUDOL SAPONE, P.C.

Dated: 29 December 2008

By: 

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APPENDIX A: Claims on Appeal

1. An endoscopic medical instrument comprising an elongate tubular member with a lumen and a plurality of hollow needle elements connected to one end of said elongate member so that each of said hollow needle elements communicates at a proximal end with said lumen of said elongate tubular member, said elongate tubular member being sufficiently flexible, long and narrow to traverse a biopsy channel of a flexible fiberoptic endoscope, said needle elements extending in a direction away from said one end of said elongate tubular member, said needle elements each being convex on an outer side facing away from others of said needle elements and concave on an inner side facing said others of said needle elements so that said needle elements together define a bulbous ovoid shape, with tips of said needle elements angled inwardly at a distal tip of the medical instrument, said needle elements each being sufficiently flexible to negotiate bends in said biopsy channel, each of said hollow needle elements being provided with at least one aperture so that fluid may be delivered through said elongate tubular member into said hollow needle elements and out through the apertures in said hollow needle elements.

3. The medical instrument defined in claim 1 wherein said needle elements

are at least partially made of resilient material with a memory so that said needle elements are alternately disposable in (a) a collapsed storage configuration inside said elongate member and (b) said bulbous ovoid shape.

4. The medical instrument defined in claim 3 wherein said needle elements are disposable in said storage configuration by the application of an external force, said needle elements having an internal spring bias tending to restore said needle elements to said bulbous ovoid shape.

5. The medical instrument defined in claim 1, further comprising at least one straight or linear hollow needle element connected to said elongate member proximate to said one end thereof, said at least one straight or hollow linear needle element being provided with at least one aperture.

APPENDIX B: Claims Support and Drawing Analysis Section

Claim 1 reads:

1. An endoscopic medical instrument comprising an elongate tubular member with a lumen and a plurality of hollow needle elements connected to one end of said elongate member so that each of said hollow needle elements communicates at a proximal end with said lumen of said elongate tubular member **{page 20, lines 8-12}**, said elongate tubular member being sufficiently flexible, long and narrow to traverse a biopsy channel of a flexible fiberoptic endoscope **{page 6, lines 13; page 20, lines 22-22; page 22, lines 3-4}**, said needle elements extending in a direction away from said one end of said elongate tubular member **{page 21, lines 9-13}**, said needle elements each being convex on an outer side facing away from others of said needle elements and concave on an inner side facing said others of said needle elements so that said needle elements together define a bulbous ovoid shape **{page 21, lines 9-13}**, with tips of said needle elements angled inwardly at a distal tip of the medical instrument **{page 21, lines 9-13}**, said needle elements each being sufficiently flexible to negotiate bends in said biopsy channel **{page 4, lines 12-15; page 8, lines 11-13; page 17, lines 21-22; page 18, lines 8-9; page 21, lines 4-8; page Figure 3}**, each of said hollow needle elements being provided with at least one aperture so that fluid may be delivered through said elongate tubular member into said hollow needle elements and out through the apertures in said hollow needle elements **{page 7, lines 14-15; page 21, lines 16-18.}**.

APPENDIX C: Means or Step Plus Function or Analysis Section

None of the claims on appeal are believed to have a means- or step-plus-function element.

APPENDIX D: Evidence Section

Table of Contents:

Not applicable: no contents in this section.

Appellant has not submitted any special evidence. The evidence to be considered on appeal consists of Appellant's disclosure and the prior art relied on by the Examiner.

APPENDIX E: Affidavits and Declarations

No affidavit or declaration has been submitted in this case.

APPENDIX F: Other Evidence Filed Prior to the Notice of Appeal

No evidence was filed prior to the Notice of Appeal.

APPENDIX G: Other Evidence Filed After the Notice of Appeal

No evidence was filed after the Notice of Appeal.